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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David S. Lawrence

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EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,009	<b>Applicant(s)</b> LAWRENCE ET AL.	
	<b>Examiner</b> Jake M. Vu	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,11,144,145 and 150 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,11,144,145 and 150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Amendment filed on 01/13/2010.

- Claim 1 has been amended.
- Claim 150 has been added.
- Claims 1-2, 4-8, 11, 144-145 and 150 are pending in the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires the ligand to be a steroid. Claim 5, which depends on claim 1, recites ligands, such as “3,5-di-tert-butyl-4-hydroxy-N-isobutyl-benzamide” and “dibenzoylhydrazine”, which are not steroids. Please clarify.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 11, 144-145 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over KAO et al (US 6,803,479) **are withdrawn** in view of Applicant's Amendment.

However, upon further consideration of Applicant's Amendment, a new ground(s) of rejection is made as discussed below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6-7, 11, 144-145 rejected under 35 U.S.C. 102(e) as being anticipated by KAO et al (US 6,803,479).

Applicant's claims are directed to a compound comprising of: a steroidal ligand not naturally present in animals; and a molecular cage, such a nitromethoxybenzyl moiety, such as 1-methyl-4,5-dimethoxy-2-nitrobenze. Additional limitations include: two-photon cage; and 325-375nm wavelengths.

KAO teaches a compound comprised of: a caged antiprogestins, such as mifepristone (see col. 5, line 60-65), which is a synthetic steroidal ligand (see col. 12,

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line 58-60) not naturally present in mammals; and a molecular cage, such a nitromethoxybenzyl moiety (see col. 16, line 46-60), such as 1-methyl-4,5-dimethoxy-2-nitrobenze (see figure 11). Additional limitations include: two-photon cage (see col. 16, line 39-40 and line 20-27); and 360nm wavelength (see figure 11; col. 16, line 25-26); photochemically transform by light to yield free (see col. 1, line 13-14); caging group must be covalent linked (see col. 16, line 14-15).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-8, 11, 144-145 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over KAO et al (US 6,803,479).

As discussed above, KAO teaches a compound comprised of: a caged antiprogestins, such as mifepristone (see col. 5, line 60-65), which is a synthetic steroidal ligand (see col. 12, line 58-60) not naturally present in mammals; and a molecular cage, such a nitromethoxybenzyl moiety (see col. 16, line 46-60), such as 1-methyl-4,5-dimethoxy-2-nitrobenze (see figure 11). Additional limitations include: two-photon cage (see col. 16, line 39-40 and line 20-27); and 360nm wavelength (see figure 11; col. 16, line 25-26); photochemically transform by light to yield free (see col. 1, line

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13-14); caging group must be covalent linked (see col. 16, line 14-15); and ecdysones, such as 20-hydroxy-ecdysone, muristerone A and ponasterone A (see col. 15, line 7-11).

KAO does not specifically teach caging ecdysone.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate ecdysones, such as 20-hydroxy-ecdysone into KAO's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would be another way to study gene expression system (see col. 5, line 63-67), and reasonably would have expected success because the ecdysones have direct hydroxyl functional groups (see Figure 9) similar to mifepristone that can form cages (see col. 13, line 14-22 and Figure 7).

### ***Response to Arguments***

Applicant argues that Kao discusses the possibility of caging the steroid mifepristone, an idea that Kao rejects. Kao notes "Our somewhat limited experience with bioactive steroids, however, is that they prone to side reactions, and chemical manipulations often require extensive use of protective groups to block such unwanted reactions. As a starting point for testing the concept of a photochemical gene switch, steroid-based inducers may prove intractable." Similarly, in Column 15, Kao rejects the idea of using the steroids ponasterone A and muristerone A to prepare caged compounds. Kao notes at lines 11-13 "That these ecdysone analogues are steroids presents the same chemical obstacle to caging as did mifepristone. The Examiner finds this argument unpersuasive, because from column 12 to column 16, Kao is merely

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discussing the pros and cons of the different types of inducible gene expression methods, wherein KAO also mentioned the drawback of the ecdysone-inducible system (see col. 15, line 39-48), which is the nonsteroidal ecdysone mimetic system, but decides that the best mode is the ecdysone-inducible system (see col. 16, line 1-8). Additionally, KAO specifically teach caging steroidal ligands, such as mifepristone (see col. 5, line 55-67 under "Variations and altered forms of the Invention").

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/  
Primary Examiner, Art Unit 1618